C.S. B2: Observational Study Involving Patient Questionnaires (written) and Patient Interviews

Overview

This study examines the impact of spirituality on health status and will to live in patients with HIV/AIDS.

Subjects & Sample Size

Subjects are 100 veterans with HIV/AIDS at two VA medical centers.

Data Collection

Subjects will be interviewed in person at the beginning of the study and again 15 months later to collect demographic and clinical data. Subjects will also complete a battery of questionnaires that glean information about health status, quality of life, spirituality, etc.

In participating clinics the study is identified as a "health values study" rather than an HIV/AIDS-related study, so that observers will not be able to determine a patient's HIV status by his/her participation.

Identifying information retained for follow-up is stored separately from collected data, which is entered into a database without identifying information. All electronic data sets are maintained in password protected files. Study documents are stored in a locked cabinet.

Questions:

1. Is a waiver of informed consent or written informed consent appropriate? [*Link*]

2. Is a waiver of HIPAA authorization appropriate? [*Link*]

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[From OHRP Web site: www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm]

1. Is a waiver of informed consent or written informed consent appropriate?

Chart 10: Can informed consent be waived or consent elements be altered under 45 CFR 46.116(c) or (d)?

Will the research involve greater than minimal risk[1], as defined in Section 46.102(i)? [45 CFR 46.116(d)(1)]

YES

No waiver of informed consent or alteration of consent elements is allowed.
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Chart 11: Can documentation of informed consent be waived under 45 CFR 46.117(c)?

Would the consent document be the only ***record linking the subject and the research***[2]
and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than ***minimal risk***[3] and involve no procedures
for which written consent is ***normally required outside the research context***[4]? [45 CFR 46.117(c)(2)]

NO

IRB may not waive the requirement for a signed consent form for any subjects.

Notes for C.S. B2: Q1

[1]**Definition:** "Minimal risk means that the ***probability*** and ***magnitude*** of harm or discomfort anticipated in the research are not greater in and of themselves than those ***ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"*** (CFR 46.102(1)).

Discussion: The majority of panel members felt that this study is greater than minimal risk, because a group of patients with a stigmatized illness is being asked to respond to potentially sensitive questions. The sensitive nature of the questions encompasses two concerns: (1) the potential desire by respondents to keep their personal spiritual beliefs confidential; and (2) the greater potential for questions about religion, sin, God's punishment, etc. to cause distress in this population than in the general population. The specific content of the questions would need to be reviewed and the potential for significant harm assessed.

One panel member also expressed concern about the possible burden of the questionnaire, if the subjects are especially debilitated. If this were true it would be important to ensure that subjects understand they have the right to decline participation at any time.

Several panel members considered this study to be minimal risk. The risk to the patient of participating in this study is potential loss of confidentiality. These members felt that the ***probability and magnitude*** of harm from loss of confidentiality, given the safeguards described, are no greater than ***that which is encountered in daily life or during the performance of routine physical or psychological examinations or tests.*** E.g., there is an equal or greater probability of loss of confidentiality of sensitive health data from their medical records, physicians, or friends and family. The small probability of loss of confidentiality is based on the assumption that the safeguards for maintaining data confidentiality by the investigators are sufficient and are as good as those used elsewhere in the health care facility for ensuring the confidentiality of health-related data. Therefore, sufficient information must be provided by investigators to the IRB committee for them to determine that the procedures for maintaining data confidentiality are acceptable.

The magnitude of harm from loss of confidentiality must also be considered in addition to the probability. In this case the magnitude of harm could be quite significant—such as social stigma or adverse economic consequences. Is this harm any greater than what the average person would be subjected to, if his/her sensitive health data were revealed? Some would argue that the average person is not subjected to stigmatization or potential job loss with the revelation of their health data (absolute interpretation of daily risks); but others argue that patients with HIV/AIDS are routinely subjected to risks of this magnitude (relativistic interpretation of daily risks). Those arguing that this study is no greater than minimal risk tend to interpret risks from a relativistic perspective and/or consider the probability of risk so low that it outweighs any concern regarding the magnitude.

Finally, those arguing for a minimal risk designation consider the potential distress caused by the survey questions to be no greater than questions the subjects are likely to encounter in routine physical or psychological examinations or tests, or from visits with friends and family.

For further discussion of the relativistic vs. absolute interpretation of daily life risks, see Resnik DB. Eliminating the daily life risks standard from the definition of minimal risk. J Med Ethics 2005;31:35-38. [*A link to this article is included on the home page.*]

Notes for C.S. B2: Q1 ***(cont.)***

[2]**Definition:** The investigators are maintaining a file of identifiers that can be linked to the subjects.

[3]**Definition:** "Minimal risk means that the ***probability*** and ***magnitude*** of harm or discomfort anticipated in the research are not greater in and of themselves than those ***ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"*** (CFR 46.102(1)).

Discussion: The majority of panel members considered this study to be greater than minimal risk. See discussion for note #1. However, several members disagreed, and considered the study to be minimal risk.

[4]**Discussion:** The panel members who considered the study to be minimal risk also felt that written consent is not usually required by the VA when patients answer questions or are interviewed about these topics. In this case, informed consent could be obtained via an information sheet, and documentation of informed consent would not be necessary.

Notes for C.S. B2: Q2

2. Is a waiver of HIPAA authorization appropriate?

The majority of the panel felt that the study does not meet HIPAA waiver criteria #2 below.

(1) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals based on at least the presence of:

- an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure;*
- an adequate plan to destroy those identifiers at the earliest opportunity consistent with the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law;* and
- adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI is permitted by the Privacy Rule.*

(2) The research could not practicably be conducted without the alteration or waiver; and

(3) The research could not practicably be conducted without access to and use of the PHI.

**The investigator would need to provide an adequate plan/assurances in the proposal.*